UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. NOVITIUM PHARMA, LLC, Defendant, v. BIONPHARMA INC., Intervenor-Defendant (Motion Pending)	)	C.A. No. 22-5860-ES-ESK **Motion Returnable: November 7, 2022** **ORAL ARGUMENT REQUESTED**

DEFENDANT NOVITIUM'S AND PROPOSED INTERVENOR-DEFENDANT BIONPHARMA'S OPENING BRIEF IN SUPPORT OF THEIR JOINT MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
’008 patent	U.S. Patent No. 9,669,008 B1 (C.A. No. 21-12870 ECF[*] No. 9-3, 7/13/21 Shrestha Decl. Ex. C)
’023 patent	U.S. Patent No. 11,040,023 B2 (ECF No.[†] 1-1, Compl. Ex. A)
’405 patent	U.S. Patent No. 11,141,405 B2 (ECF No. 1-2, Compl. Ex. B)
’442 patent	U.S. Patent No. 9,808,442 B2 (C.A. No. 21-12870 ECF No. 9-4, 7/13/21 Shrestha Decl. Ex. D)
’482 patent	U.S. Patent No. 10,786,482 B2 (C.A. No. 21-12870 ECF No. 9-12, 7/13/21 Shrestha Decl. Ex. L)
’587 application	U.S. Patent Application No. 17/150,587, the prosecution history of which is attached as Ex. V to the 7/13/21 Shrestha Declaration (C.A. No. 21-12870 ECF No. 9-22)
’587 PH	Prosecution history of the ’587 application, attached as Ex. V to the 7/13/21 Shrestha Declaration (C.A. No. 21-12870 ECF No. 9-22)
’621 patent	U.S. Patent No. 10,918,621 B2 (C.A. No. 21-12870 ECF No. 9-13, 7/13/21 Shrestha Decl. Ex. M)
’745 patent	U.S. Patent No. 10,039,745 B2 (C.A. No. 21-12870 ECF No. 9-5, 7/13/21 Shrestha Decl. Ex. E)
’747 patent	U.S. Patent No. 8,568,747 B1 (C.A. No. 21-12870 ECF No. 43-9, 8/26/21 Moreton Decl. Ex. Q)
21-12870 action	*Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, No. 3:21-cv-12870-MAS-DEA (D.N.J.)
Amneal	Third-party Amneal Pharmaceuticals LLC
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc., successor-in-interest to Silvergate Pharmaceuticals, Inc.
Azurity’s enalapril oral liquid patents or patent family	’008, ’442, ’745, ’987, ’482, ’868,’621, ’023, and ’405 patents
Azurity’s 21-12870 TRO/PI Motion	C.A. No. 21-12870 ECF No. 24, Azurity’s Motion for Order to Show Cause for Temporary Restraining Order, Preliminary Injunction, and Other Emergent Relief

[*] “C.A. No. 21-12870 ECF No.” or “21-12870 ECF No.” shall refer to docket entries in *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, No. 3:21-cv-12870-MAS-DEA (D.N.J.).
[†] “All “ECF” citations shall be to the docket in the instant suit unless otherwise specified.

Abbreviation	Meaning
Azurity's 21-12870 TRO/PI Motion Brief	C.A. No. 21-12870 ECF No. 25, Brief in Support of Azurity's Order to Show Cause for Temporary Restraining Order, Preliminary Injunction, and Other Emergent Relief
Azurity's Opposition to Bionpharma's 21-12870 MTT	C.A. No. 21-12870 ECF No. 31, Azurity's Opposition to Defendant's Motion to Transfer
Bionpharma	Proposed Intervenor-Defendant Bionpharma Inc.
Bionpharma's ANDA	Bionpharma's ANDA No. 212408
Bionpharma's 21-12870 Motion to Dismiss or Bionpharma's 21-12870 MTD	C.A. No. 21-12870 ECF No. 8, Bionpharma's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)
Bionpharma's 21-12870 Motion to Dismiss Brief or Bionpharma's 21-12870 MTD Br.	C.A. No. 21-12870 ECF No. 8-1, Bionpharma's Brief in Support of Its Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)
Bionpharma's 21-12870 Motion to Transfer or Bionpharma's 21-12870 MTT	C.A. No. 21-12870 ECF No. 7, Bionpharma's Motion to Transfer Venue Pursuant to 28 U.S.C. § 1404(a)
Bionpharma's 21-12870 Opening MTT Brief	C.A. No. 21-12870 ECF No.7-1, Bionpharma's Brief in Support of tis Motion to Transfer Venue Pursuant to 28 U.S.C. § 1404(a)
Bionpharma's 21-12870 TRO/PI Opposition	C.A. No. 21-12870 ECF No. 38, Bionpharma's Opposition to Plaintiff Azurity's Motion for Order to Show Cause with Temporary Restraints, Preliminary Injunction, and Other Emergent Relief
CCLS	Counterclaims
The common specification	The common specification of Azurity's enalapril oral liquid patent family
CoreRx	Third-party CoreRx, Inc., Bionpharma's previous contract manufacturer and ANDA product supplier
The Delaware Suits	The First, Second, and Third Wave Suits
DOE	Doctrine of equivalence
Epaned® Kit or the Kit	Azurity's predecessor product to Epaned® (21-12870 ECF No. 9-7, 7/13/21 Shrestha Decl. Ex. G, Op. at 7)
First Wave Patents	'008, '442, '745, and '987 patents
First Wave Suits	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.)
JSD	Joint stipulation of dismissal
8/26/21 Moreton Decl.	C.A. No. 21-12870 ECF No. 42, August 26, 2021 Declaration of R. Christian Moreton, Ph.D.
NDA	New Drug Application pursuant to 21 U.S.C. § 355(b)(1)

Abbreviation	Meaning
Novitium	Defendant Novitium Pharma, LLC
Paragraph IV certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
Patents-in-suit	The ’023 and ’405 patents
PI	Preliminary injunction
POSA	Person of ordinary skill in the art
PTO or Patent Office	United States Patent and Trademark Office
Second Wave Patents	’868, ’482, and ’621 patents
Second Wave Suit	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.)
7/13/21 Shrestha Declaration	C.A. No. 21-12870 ECF No. 9, July 13, 2021 Declaration of Roshan P. Shrestha, Ph.D.
8/26/21 Shrestha Declaration	C.A. No. 21-12870 ECF No. 40, August 26, 2021 Declaration of Roshan P. Shrestha, Ph.D.
Third Wave Suits	*Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 21-1286 and 21-1455 (D. Del.)

Defendant Novitium and proposed Intervenor-Defendant Bionpharma submit the instant Opening Brief in support of their Joint Motion to Transfer Venue Pursuant to 28 U.S.C. § 1404(a).

INTRODUCTION

Bionpharma and Plaintiff Azurity have been litigating the accused product in this suit—Bionpharma's 1 mg/ml enalapril maleate oral solution ("Bionpharma's ANDA product"), approved under Bionpharma's ANDA No. 212408 ("Bionpharma's ANDA") as generic to Azurity's Epaned® antihypertensive prescription drug product—and Azurity's enalapril oral liquid patent family for the last four years in the District of Delaware, across three waves of litigation. The First Wave Suits,[1] which Azurity began filing in December of 2018 and which involved Azurity's first generation enalapril oral liquid patents, were resolved in Bionpharma's favor after a 5-day bench trial before then-Chief Judge Leonard P. Stark, who entered judgment of non-infringement in Bionpharma's favor on April 29, 2021. Because of Judge Stark's decision in the First Wave Suits, Azurity conceded that it could not prove infringement in the Second Wave Suit,[2] which involved broader patents that Azurity began securing in September of 2020, and Azurity agreed to dismissal of that suit with prejudice.

Then—in a blatant attempt to avoid an adverse judgment and numerous other adverse rulings from the First and Second Wave Suits—Azurity filed what would eventually become the first of the Third Wave Suits[3] here in the District of New Jersey on June 22, 2021. *See Azurity Pharm., Inc. v. Bionpharma Inc.*, No. 3:21-cv-12870 (MAS) (DEA) (D.N.J.) ("the 21-12870

[1] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-MSG, 19-1067-MSG (D. Del.). Azurity is the successor-in-interest to Silvergate Pharmaceuticals, Inc. 21-12870 ECF No. 1, Compl. ¶ 3; 21-12870 ECF No. 56, Mem. Op. at 3 n.1.
[2] *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-MSG (D. Del.).
[3] *Azurity Pharm. v. Bionpharma Inc.*, C.A. Nos. 21-1286-MSG, 21-1455-MSG (D. Del.).

action"). The 21-12870 action was assigned to the Honorable Michael A. Shipp, who—less than three months after the case was filed—blocked Azurity's attempt to avoid Delaware by granting a § 1404(a) motion that Bionpharma had filed and transferred the case back to the District of Delaware. 21-12870 ECF Nos. 56 (Mem. Op.) and ECF No. 57 (Order transferring case to the District of Delaware ("Transfer Order")).

Now, in a remarkable attempt to contravene Judge Shipp's Transfer Order, Azurity has instituted the instant action, which accuses the same product (Bionpharma's ANDA product) of infringing essentially the same patent rights—the '023 patent, which was asserted in the 21-12870 action, and the later-issued, but related, '405 patent, which claims essentially the same subject matter claimed in the '023 patent. That Azurity has named Novitium, Bionpharma's current ANDA product supplier, as a defendant in this suit is of no moment; like Bionpharma, Novitium is a Delaware corporation and Azurity could have—and in fact should have, in light of Judge Shipp's Transfer Order—sued Novitium in Delaware. Because of the undeniable overlap in parties and subject matter, this action is indisputably related to the 21-12870 action that Judge Ship transferred to Delaware last year, and Judge Shipp's Transfer Order is thus the law of the case in the instant action. Further, Azurity is collaterally estopped from re-litigating Judge Shipp's Transfer Order and, in particular, His Honor's determination and conclusion underlying that order that "a consideration of the private and public interest factors weighs strongly in favor of transfer." 21-12870 ECF No. 56, Mem. Op. at 20.

Even if this Court is inclined to re-decide this issue, the public interest factors strongly support transfer of this case to Delaware, where (1) the Third Wave Suits, which involve the same asserted patents and accused subject matter (Bionpharma's ANDA product), have been pending for over the last year; (2) Bionpharma has a pending motion to dismiss Azurity's Third Wave Suits

on claim preclusion grounds based on the Delaware court's judgment of non-infringement in the First Wave Suits and dismissal of the Second Wave Suit with prejudice; (3) Azurity has sued Bionpharma no less than four times involving the same subject matter; and (4) there are currently three related pending suits against other ANDA-sponsors, including one that involves the same asserted patents. Maintaining the instant suit in this Court would risk unnecessary duplication of effort and inconsistent rulings.

For the foregoing reasons, explained more fully below, Bionpharma and Novitium respectfully request transfer of the instant action to the District of Delaware pursuant to § 1404(a).

FACTUAL BACKGROUND

I. THE FIRST WAVE SUITS

Bionpharma is a generic drug company that develops and commercially markets affordable quality generic medications. In 2018, Bionpharma prepared and filed its ANDA with the FDA. 12-12870 ECF No. 1, Compl. ¶ 14. In response, Azurity filed the First Wave Suits starting in December of 2018 in Delaware Federal court, asserting that Bionpharma's ANDA and the product described therein infringe Azurity's '008, '442, '745, and '987 patents ("First Wave Patents"). 21-12870 ECF Nos. 9-1, 9-2, 7/13/21 Shrestha Decl. Exs. A and B, First Wave Suits complaints; 21-12870 ECF No. 56, Mem. Op. at 3. The claims of Azurity's First Wave Patents are directed to: (1) a group of enalapril liquid formulations that contain citric acid and sodium citrate as a buffer system at specific concentrations, sodium benzoate as a preservative at specific concentrations, and that are stable for 12 months at refrigerated conditions; and (2) methods of treatment using those liquids. 21-12870 ECF Nos. 9-3, 9-4, 9-5, 9-6, 7/13/21 Shrestha Decl. Exs. C-F, First Wave Patents at claims; 21-12870 ECF No. 9-7, 7/13/21 Shrestha Decl. Ex. G, Op. at 15-19. Bionpharma had designed its ANDA product extensively around Azurity's First Wave Patents, including by

omitting a buffer entirely, and by utilizing an alternative to the claimed sodium benzoate preservative. 21-12870 ECF No. 9-7, 7/13/21 Shrestha Decl. Ex. G, Op. at 7-9.

The Delaware court held a five-day bench trial on February 1-5, 2021 and, on April 27, 2021, issued its Opinion finding the asserted claims of Azurity's First Wave Patents not infringed by Bionpharma's ANDA product, including because Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product. *Id*. at 1, 64-66; 21-12870 ECF No. 56, Mem. Op. at 4. The court entered final judgement in Bionpharma's favor shortly thereafter, which was summarily affirmed on appeal. 21-12870 ECF No. 9-8, 7/13/21 Shrestha Decl. Ex. H, Final J.; *Azurity Pharm., Inc. v. Bionpharma Inc.*, No. 2021-1926, 1927, 2022 WL 703903 (Fed. Cir. Mar. 9, 2022).

II. THE SECOND WAVE SUIT

Shortly after Bionpharma filed its ANDA, Azurity began filing patent applications seeking considerably broader and different claim coverage, and eventually secured issuance of the '868, '482, and '621 patents ("Second Wave Patents") in late 2020 and early 2021, which were the subject of Azurity's Second Wave Suit. 21-12870 ECF No. 9-10, 7/13/21 Shrestha Decl. Ex. J, Second Wave Suit, ECF No. 49, Second Am. Compl.; 21-12870 ECF Nos. 9-11, 9-12, 9-13, 7/13/21 Shrestha Decl. Exs. K-M, Second Wave Patents at covers; 21-12870 ECF No. 56, Mem. Op. at 3.

As explained above, on April 27, 2021, the Delaware court issued its opinion in the First Wave Suits finding that, *inter alia*, Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product. Because all of the Second Wave Patents' claims require a buffer (21-12870 ECF Nos. 9-11, 9-12, 9-13, 7/13/21 Shrestha Decl. Exs. K-M, Second Wave Patents at claims), Azurity conceded that it could not prove infringement of the Second Wave Patents, and

the parties ultimately stipulated to dismissal of the Second Wave Suit with prejudice. 21-12870 ECF No. 9-15, 7/13/21 Shrestha Decl. Ex. O, JSD; 21-12870 ECF No. 56, Mem. Op. at 4.

III. THE THIRD WAVE SUITS

On January 15, 2021, over two years after Bionpharma filed its ANDA with FDA and the commencement of the First Wave Suits, Azurity filed with the PTO U.S. Patent Application No. 17/150,587, which claims priority to the First and Second Wave Patents. ECF No. 1-1, Compl. Ex. A, '023 patent at cover. On June 22, 2021, the '587 application issued into the '023 patent. *Id*. The claims of the '023 patent are similar to the claims of the First and Second Wave Patents, with the only difference being that the enalapril liquids claimed in the '023 patent may contain, but do not explicitly require, a buffer. ECF No. 1-1, Compl. Ex. A, '023 patent at claims.

The same day the '023 patent issued, Azurity instituted the 21-12870 action in this District alleging that Bionpharma's ANDA and ANDA product infringe the claims of the '023 patent. 21-12870 ECF No. 1, Compl. In response, Bionpharma filed motions to: (1) transfer the 21-12870 action pursuant to 28 U.S.C. § 1404(a) to the District of Delaware; and (2) dismiss the complaint under Fed. R. Civ. P. 12(b)(6) on claim preclusion grounds. C.A. No. 21-12870 ECF Nos. 7, 8. Shortly after Bionpharma secured final FDA approval of its ANDA (August 10, 2021), and launched its ANDA product (on or about August 17, 2021), Azurity moved for an order to show cause for a temporary restraining order, preliminary injunction, and other emergent relief in an effort to remove Bionpharma's competing product from the market. C.A. No. 21-12870 ECF No. 24 ("Azurity's 21-12870 TRO/PI Motion").

On September 20, 2021, Judge Shipp blocked Azurity's attempt to avoid the District of Delaware and granted Bionpharma's 21-12870 Motion to Transfer. C.A. No. 21-12870 ECF No. 56, Mem. Op. The 21-12870 action was thereafter transferred back to the District of Delaware,

where it was assigned Civil Action No. 21-1286. After transfer, the Delaware court denied Azurity's 21-12870 TRO/PI Motion, finding that, *inter alia*, Bionpharma had raised "substantial questions" regarding the '023 patent's validity. D. Del C.A. No. 21-1286-MSG[4] ECF No. 87, Oral Order; D. Del C.A. No. 21-1286-MSG ECF No. 96, 11/10/21 Hr'g Tr. 103:19-24, 115:11-17.

On October 15, 2021, Azurity secured issuance of the '405 patent—the latest patent in its enalapril oral liquid patent family. ECF No. 1-2, Compl. Ex. B, '405 patent at cover. The claims of the '405 patent are essentially duplicative of the claims of the '023 patent—they both cover genuses of enalapril liquids that may contain, but do not require, a buffer. *Id*. at claims. The same day the '405 patent issued, Azurity instituted *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-MSG (D. Del.), asserting that Bionpharma's ANDA and ANDA product infringe the '405 patent's claims. The 21-1286-MSG and 21-1455-MSG suits ("Third Wave Suits") remain pending in Delaware before Judge Goldberg.

IV. OTHER RELATED DELAWARE SUITS

The First, Second, and Third Wave Suits are not the only suits in Delaware that Azurity has instituted against ANDA sponsors for generic enalapril oral liquids. Azurity has instituted the following suits against sponsors of generic enalapril oral liquid ANDAs alleging infringement of the First, Second, and/or Third Wave Patents:

Silvergate Pharm., Inc. v. Amneal Pharm. LLC, C.A. 19-678-LPS (D. Del.)

Azurity Pharm, Inc. v. Annora Pharma Private Ltd., C.A. No. 20-753-LPS (D. Del.)

Azurity Pharm, Inc. v. Alkem Labs. Ltd., C.A. No. 19-2100-MSG (D. Del.)

Silvergate Pharm., Inc. v. Amneal Pharm. LLC, C.A. 20-1255-LPS (D. Del.)

[4] Following Judge Stark's appointment and confirmation to the United States Court of Appeals for the Federal Circuit, the Delaware Suits were reassigned to the Honorable Mitchell S. Goldberg (sitting by designation from the Eastern District of Pennsylvania).

Azurity Pharm, Inc. v. Annora Pharma Private Ltd., C.A. No. 21-196-MSG (D. Del.)

Azurity Pharm., Inc. v. CoreRx, Inc., C.A. No. 21-1522-LPS (D. Del.)

Azurity Pharm., Inc. v. Aurobindo Pharma Ltd., C.A. No. 21-1707-MSG (D. Del.)

The 19-2100-MSG (Alkem), 21-196-MSG (Annora), and 21-1707-MSG (Aurobindo) cases remain pending.

ARGUMENT

I. LEGAL STANDARD

A. Law of the Case Doctrine

"The 'law of the case' doctrine 'posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'" *Ragner Tech. Corp. v. Berardi*, 287 F. Supp. 3d 541, 546 (D.N.J. 2018) (quoting *Christianson v. Colt. Indus. Operating Corp.*, 486 U.S. 800, 815-16 (1988)). "Law of the case rules have developed to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." *Casey v. Planned Parenthood*, 14 F.3d 848, 856 (3d Cir. 1994) (internal quotations omitted). "[L]aw of the case rules apply to subsequent rulings by the same judge in the same case or a closely related one, to rulings by different judges at the same level, or to the consequences of the failure to preserve an issue for appeal." *Id.* at 856 n.11; *see also Jersey Dental Labs. v. Dentsply Int'l, Inc.*, No. Civ.A. 01-267-SLR, 2002 WL 2007916, at *1 (D. Del. Aug. 27, 2002) ("[T]he court will refrain from redeciding issues that were resolved earlier in the closely related litigation." (citations and internal quotations and brackets omitted)).

B. Collateral Estoppel (Issue Preclusion)

The Third Circuit has "identified four standard requirements for the application of collateral estoppel . . . : (1) the identical issue was previously adjudicated; (2) the issue was

actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir.2006) (citations and internal quotations omitted). Courts in the Third Circuit are also to consider "whether the party being precluded had a full and fair opportunity to litigate the issue in question in the prior action, . . . , and whether the issue was determined by a final and valid judgment." *Id*. (internal citations and quotations omitted). Further, "[t]here is no bright-line rule regarding what constitutes a 'final judgment' for issue preclusion." *Free Speech Coal. v. Att'y Gen. of U.S.*, 677 F.3d 519, 541 (3d. Cir. 2012). "Instead, [the Third Circuit has] found that a prior adjudication of an issue in another action must be 'sufficiently firm' to be accorded conclusive effect." *Id*. (citations omitted); *see also In re Brown*, 951 F.2d 564, 569 (3d Cir. 1991) ("Unlike claim preclusion, the effectiveness of issue preclusion, sometimes called collateral estoppel, does not require the entry of a judgment, final in the sense of being appealable."). Non-determinative "[f]actors that courts consider when determining whether the prior determination was sufficiently firm include: whether the parties were fully heard, whether a reasoned opinion was filed, and whether that decision could have been, or actually was, appealed." *Free Speech*, 677 F.3d at 541 (citations and internal quotations omitted).

C. 28 U.S.C. § 1404(a)

Pursuant to § 1404(a), a district court may transfer a civil action to another district where the action may have been brought "[f]or the convenience of parties and witnesses, in the interest of justice." "The purpose of Section 1404(a) is to prevent the waste of time, energy and money and to protect litigants, witnesses and the public against unnecessary inconvenience and expense." *Wm. H. McGee & Co. v. United Arab Shipping Co.*, 6 F. Supp. 2d 283, 287 (D.N.J. 1997) (citations

and quotation marks omitted). The Third Circuit has articulated a list of twelve public and private interest factors for the district courts to consider when weighing whether an action should be transferred. *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879-80 (3d Cir. 1995).

II. THE INSTANT SUIT SHOULD BE TRANSFERRED TO THE DISTRICT OF DELAWARE

In what appears to be yet ***a second attempt*** by Azurity in a little over a year to avoid an adverse judgment and numerous adverse rulings from the District of Delaware, including a ruling denying Azurity's request for emergent relief based on the same patent rights asserted in the instant suit, Azurity has filed the instant action in this Court—which is nearly duplicative of the Third Wave Suits pending for over a year in Delaware—in contravention of Judge Shipp's Transfer Order. That Azurity has named Bionpharma's current ANDA product manufacturer and supplier—Novitium—as the defendant in the instant suit is of no moment as it does not materially change the facts from the 12-12870 action that Judge Shipp transferred to Delaware last August: (1) the accused product in this case is still Bionpharma's ANDA product (the same product that Azurity and Bionpharma have been litigating in Delaware for four years); and (2) this case involves essentially the same patent rights that Azurity asserted in the 21-12870 action. This Court should transfer the instant case to Delaware for numerous reasons (explained below), including and especially to avoid unnecessary duplication of effort and inconsistent rulings with the District of Delaware.

A. Delaware Is a Proper Forum

Novitium and Bionpharma are both incorporated in Delaware, and are thus both subject to personal jurisdiction there and venue is also proper there for both of them. ECF No. 1, Compl. ¶ 3; 21-12870 ECF No. 56, Mem. Op. at 1, 20; 28 U.S.C. § 1400(b). Azurity also resides in Delaware. ECF No. 1, Compl. ¶ 2; *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, 978 F.3d

1374, 1375 (Fed. Cir. 2020). Moreover, Azurity and Bionpharma have already been litigating in Delaware the accused product in this case (Bionpharma's ANDA product) and Azurity's enalapril oral liquid patent family for four years across five lawsuits. Thus, there can be no dispute that Delaware is a proper forum for this action.

B. Judge Shipp's Transfer Order Is the Law of the Case and Should be Followed

This case involves the same accused product that was involved in the 21-12870 action, and essentially the same patent rights—as explained above, Azurity asserted the '023 patent, which is asserted in the instant suit, in the 21-12870 action, and the related '405 patent claims essentially the same subject matter claimed in the '023 patent. Azurity and Bionpharma were the named plaintiff and defendant, respectively, in the 21-12870 action, and Novitium is merely a current supplier for Bionpharma's ANDA product.[5] Despite Azurity's failure to designate it as such, there can be no real dispute that this action is closely related to the 21-12870 action. *See* ECF No. 1, Compl. ¶ 9 (Azurity admitting that the accused product in the instant suit is the same accused product in the D. Del. C.A. No. 21-1286 suit, which was the civil action number assigned to the 21-12870 action after it was transferred). Under Third Circuit law, the law of the case doctrine applies to rulings in closely related cases, including "rulings by different judges at the same level." *Casey*, 14 F.3d at 856 n.11. There is simply no reason for this Court to "redecid[e] issues that

[5] At the very least, Bionpharma and Novitium are in privity with one another as to Bionpharma's ANDA product. *Greenway Center, Inc. v. Essex Ins. Co.*, 475 F.3d 139, 149 (3d Cir. 2007) ("Privity is defined as a mutual or successive relationship to the same rights of property. . . . or such an identification of interest of one person with another as to represent the same legal right." (internal quotations omitted); *see also Gambocz v. Yelencsics*, 468 F.2d 837, 841 (3d Cir. 1972) ("[*R*]*es judicata* may be invoked against a plaintiff who has previously asserted essentially the same claim against different defendants where there is a close or significant relationship between successive defendants."); *Lubrizol Corp. v. Exxon Corp.*, 929 F.2d 960, 966 (3d Cir. 1991) ("[A] lesser degree of privity is required" where, as here, "a new defendant [seeks] to benefit from claim preclusion than for a plaintiff to bind a new defendant in a later action.").

were resolved earlier" by Judge Shipp, including Judge Shipp's Transfer Order. *Jersey Dental*, 2022 WL 2007916, at *1.

Judge Shipp's Transfer Order was based on His Honor's conclusion that "a consideration of the private and public interest factors weighs strongly in favor of transfer." 21-12870 ECF No. 56, Mem. Op. at 19-20. This action involves essentially the same parties and patent rights, and the exact same accused product. Judge Shipp's Transfer Order should be followed, and the instant action should be transferred to the District of Delaware.

C. Azurity Is Estopped from Contesting Transfer

Judge Shipp's Transfer Order has preclusive effect and bars Azurity from challenging transfer under the doctrine of collateral estoppel (issue preclusion).

1. The Identical Issue Was Previously Adjudicated

There can be no dispute that the identical issue—whether a case involving Azurity's allegation that Bionpharma's ANDA product infringes patents in Azurity's enalapril oral liquid patent family should be transferred to the District of Delaware pursuant to 28 U.S.C. § 1404(a)—was previously adjudicated in the 21-12870 action. *See* 21-12870 ECF No. 56, Mem. Op.

2. The Issue Was Actually Litigated

There also can be no dispute that the Azurity and Bionpharma fully briefed this issue in the 21-12870 action, and that Judge Shipp issued a thorough Memorandum Opinion addressing the parties' arguments on this issue, and determining and concluding that "a consideration of the private and public interest factors weighs strongly in favor of transfer." 21-12870 ECF No. 56, Mem. Op. at 19-20.

3. The Previous Determination Was Necessary to the Decision

There can also be no dispute that Judge Shipp's determination and conclusion that "a consideration of the private and public interest factors weighs strongly in favor of transfer." *id*., was necessary to His Honor's decision to transfer the 21-12870 action to the District of Delaware, 21-12870 ECF No. 57, Transfer Order.

4. Azurity Was Fully Represented and Had a Full and Fair Opportunity to Be Heard

There can also be no dispute that Azurity was fully represented in the 21-12870 action—counsel of record in the instant suit represented Azurity in the 21-12870 action. *Compare*, ECF No. 1, Compl., *with* 21-12870 ECF No. 1, Compl. Relatedly, there can also be no dispute that Azurity had a full and fair opportunity to be heard on the issue of transfer—the parties fully briefed the issue, which was ultimately decided by Judge Shipp, who addressed Azurity's arguments in a thorough Memorandum Opinion. 21-12870 ECF Nos. 7, 31, 45, 56.

5. Judge Shipp's Transfer Order Is Final for Issue Preclusion Purposes

As explained above, "[t]here is no bright-line rule regarding what constitutes a 'final judgment' for issue preclusion." *Free Speech*, 677 F.3d at 541. "Instead, [the Third Circuit has] found that a prior adjudication of an issue in another action must be 'sufficiently firm' to be accorded conclusive effect." *Id*. (citations omitted). Importantly, "collateral estoppel [] does not require the entry of a judgment, final in the sense of being appealable." *Brown*, 951 F.2d at 569.

Here, as explained above, Azurity and Bionpharma were fully heard on the issue of whether a case involving Azurity's claim that Bionpharma's ANDA product infringes patents in Azurity's enalapril oral liquid patent family should be transferred to the District of Delaware pursuant to 28 U.S.C. § 1404(a), and Judge Shipp entered a reasoned opinion deciding that it should be. 21-12870 ECF No. 56, Mem. Op. Judge Shipp's Transfer Order (21-12870 ECF No. 57) is thus

"'sufficiently firm' to be accorded conclusive effect," *Free Speech*, 677 F.3d at 541, and, as such, Azurity is collaterally estopped from challenging transfer of the instant action to the District of Delaware.

D. Transfer Is Warranted under 28 U.S.C. § 1404(a)

Even if this Court is inclined to re-decide the issue of transfer under § 1404(a), transfer should still be granted, as a balance of the private and public interest *Jumara* factors "weighs strongly in favor of transfer." 21-12870 ECF No. 56, Mem. Op. at 19-20.

1. The Private Interest Factors Are Neutral

The private interest factors include:

> 1) the plaintiff's forum preference; 2) the defendant's forum preference; 3) where the claim arose; 4) the convenience of the parties as indicated by their relative physical and financial condition; 5) the convenience of the witnesses, but only to the extent they may be unavailable for trial in one of the fora; and 6) the location of books and records (similarly limited to the extent that they could not be produced in the alternative forum).

S. Jersey Gas Co. v. Antero Res. Appalachian Corp., No. 15-CV-1888, 2016 WL 266340, at *3 (D.N.J. Jan. 21, 2016) (quoting *Jumara*, 55 F.3d at 879).

Here, while Azurity's choice of New Jersey should be accorded some deference, it should not be accorded "paramount consideration," because New Jersey is not Azurity's home forum. ECF No. 1, Compl. ¶ 2; 21-12870 ECF No.56, Mem. Op. 6-8; *Yang v. Odom*, 409 F. Supp. 2d 599, 606 (D.N.J. 2006). Further, while Azurity's choice of New Jersey weighs against transfer, Bionpharma's and Novitium's choice of Delaware weighs in favor of transfer. 21-12870 ECF No.56, Mem. Op. 7-8.

Next, with respect to where the claim arose, courts in this District have followed a "center of gravity" approach when assessing this factor, focusing on where accused ANDA product was

researched and developed. *Teva Pharm. USA, Inc. v. Sandoz Inc.*, C.A. No. 17-275(FLW), 2017 WL 2269979, at *6-7 (D.N.J. May 23, 2017); *see also id.* at *6 (noting that some unpublished decisions look to where the infringing products are sold). Although Bionpharma's ANDA product was researched and developed in Florida—something Azurity has never disputed (21-12870 ECF No. 56, Mem. Op. at 8; *see also* 21-12870 ECF No. 9-7, 7/1/321 Shrestha Decl. Ex. G, Op. at 4, 8)—Bionpharma concedes that its ANDA product is sold nationwide; thus, this factor is neutral. 21-12870 ECF No. 56, Mem. Op. at 8-9.

With respect to the convenience of the parties, Bionpharma and Novitium concede that this factor is neutral, as all three parties are based in the Northeast. *Id.* at 9-10; ECF No. 1, Compl. ¶ 3. While Bionpharma has conceded that litigating in New Jersey would not be particularly inconvenient, 21-12870 ECF No. 56, Mem. Op. at 9-10, the fact that Bionpharma and Azurity have been litigating in Delaware for four years and have created an extensive record there counterbalances that concession. Thus, this factor is neutral. *Id*

The last two private interest factors—convenience of the witnesses and location of books and records—are neutral, as discovery in the First, Second, and Third Wave Suits has been electronic, and neither side has identified witnesses that are unavailable in any specific forum. *Id.* at 10.

Thus, as Judge Shipp found, "[o]n balance, the private interest factors are neutral." *Id.*

2. The Public Interest Factors Strongly Favor Transfer

The public interest factors include:

> 1) the enforceability of the judgment; 2) practical considerations that could make the trial easy, expeditious, or inexpensive; 3) the relative administrative difficulty in the two fora resulting from court congestion; 4) the local interest in deciding local controversies at home; 5) the public policies of the fora; and 6) the familiarity of the trial judge with the applicable state law in diversity cases.

S. Jersey Gas, 2016 WL 266340, at *3 (quoting *Jumara*, 55 F.3d at 879-80).

The "enforceability of the judgment" factor is neutral, because a judgment would be enforceable in either Delaware or New Jersey. 21-12870 ECF No. 56, Mem. Op. at 10. The practical considerations, however, strongly favor transfer, because, as explained above, Azurity and Bionpharma have been litigating Bionpharma's ANDA product and Azurity's enalapril liquid patent family in Delaware for four years now across five lawsuits. "When related actions are pending in the transferee forum, the interest of justice is generally thought to 'weigh heavily' in favor of transfer." *Samsung Elecs. Co. v. Rambus, Inc.*, 386 F. Supp. 2d 708, 721 (E.D. Va. 2005). The District of Delaware is already intimately familiar with the facts and legal questions underlying this lawsuit. During the First Wave Suits, a Delaware court sifted through massive discovery, adjudicated discovery disputes, ruled on various dispositive motions, held a five day bench trial on infringement and invalidity of patents in Azurity's enalapril oral liquid patent family, and issued a 72-page opinion finding that Bionpharma's ANDA and ANDA product do not infringe Azurity's First Wave Patents. 21-12870 ECF No. 9-7, 7/1/321 Shrestha Decl. Ex. G, Op.

More importantly, Bionpharma's ANDA product and the patents Azurity asserts in this suit are the subject of duplicative actions that have been pending in the District of Delaware for a year now—the Third Wave Suits. The parties are nearing the end of fact discovery in the Third Wave Suits and have dispositive motions on file that are currently pending, including a Rule 12(c) motion for judgment on the pleadings that Bionpharma has filed based on claim preclusion arising from the judgement of non-infringement entered in the First Wave Suits, and the dismissal with prejudice of the Second Wave Suit. D. Del. 21-1286 ECF No. 126, Scheduling Order; D. Del. 21-1286 ECF Nos. 172, 173, 181, 187 (Bionpharma's pending Rule 12(c) motion and briefing regarding same). Last November, the Delaware court denied Azurity's 21-12870 TRO/PI Motion

after the 21-12870 action was transferred because of persuasive evidence Bionpharma put forward of invalidity of the '023 patent, one of the two patents Azurity asserts in the instant suit—a ruling that would have preclusive effect as to any emergency relief Azurity attempts to seek in this case.[6] "[T]he interests of justice strongly support a transfer to [a] court that reviewed and decided [a] prior litigation between the parties and their privies, especially [where the] case turns on the preclusive effect of that court's [prior] judgment." *Weinberger v. Tucker*, 391 F. Supp. 2d 241, 245 (D. D.C. 2005). The District of Delaware is in the best position to rule on (1) Bionpharma's and Novitium's claim preclusion defense based on the First and Second Wave Suits, and (2) any motion for emergency relief that Azurity intends to bring in light of that court's denial of Azurity's 21-12870 TRO/PI motion involving the same accused product (Bionpharma's ANDA product) and the same patent rights asserted in the instant suit. Furthermore, as explained above, beyond the Third Wave Suits, there are three other related litigations currently pending against other enalapril oral liquid ANDA sponsors. As Judge Shipp found, "th[e practical considerations] weighs very strongly in favor of transfer." 21-12870 ECF No. 56, Mem. Op. 11-17.

Next, for all of the reasons detailed in Judge Shipp's Memorandum Opinion (21-12870 ECF No. 56) at pages 17-18, the court congestion factor also weighs strongly in favor of transfer, as "Federal courts in New Jersey are in the middle of a judicial emergency[, while F]ederal courts in the District of Delaware are not." *Id*. at 17.

Finally, Bionpharma and Novitium concede that the local interest, public policy, and controlling state law factors are neutral, as "patent litigation does not constitute a local controversy

[6] *Rosedale Manor Assocs., LLP v. Borough of Madison, N.J.*, C.A. No. 04-341 (JCL), 2005 WL 8175463, at *3-4 (D.N.J. Aug. 16, 2005); *Hayes v. Ridge*, 946 F. Supp. 354, 364-66 (E.D. Pa. 1996), *aff'd*, 216 F.3d 1076 (3d Cir. 2000); *Vital Pharm. v. PepsiCo, Inc.*, 528 F. Supp. 3d 1295, 1299-1304 (S.D. Fla. 2021).

in most cases," *Celletis S.A. v. Precision Bioscis., Inc.*, 858 F. Supp. 2d 376, 384 (D. Del. 2012), and no specific public policies or state laws are implicated. *See also* 21-12870 ECF No. 56, Mem. Op. at 18-19.

CONCLUSION

Judge Shipp has already ruled in the 21-12870 action that a case involving Azurity's claims that Bionpharma's ANDA product infringes patents in Azurity's enalapril liquid patent family is more properly before the District of Delaware, and His Honor ordered the 21-12870 action transferred there. In contravention of Judge Shipp's Transfer Order, Azurity has filed the instant suit in this Court, which is nearly identical to the 21-12870 action, in what appears to be yet another attempt by Azurity to avoid an adverse judgment and adverse rulings from Delaware. Judge Shipp blocked Azurity's attempt to evade Delaware once and—whether under the law of the case doctrine or collateral estoppel—Judge Shipp's decision should be followed here and this case should be transferred to Delaware, where it belongs. That Novitium has been named as the defendant does not change the calculus or conclusion here, as Novitium is simply a current supplier of Bionpharma's ANDA product—the same accused product in the 21-12870 action that was transferred to Delaware, and the same accused product in the First, Second, and Third Wave Suits, which were all filed in and/or remain pending in Delaware. Finally, even if this Court is inclined to re-decide this issue, as explained above, a balance of the private and public interest factors strongly favors transfer, as Judge Shipp has already found.

Dated: October 14, 2022

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